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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,698	07/13/2001	Gary Ketner	03940055aa	4755
30743	7590	05/05/2004	EXAMINER HILL, MYRON G	
WHITHAM, CURTIS & CHRISTOFFERSON, P.C. 11491 SUNSET HILLS ROAD SUITE 340 RESTON, VA 20190			ART UNIT 1648	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,698

Applicant(s)

KETNER, GARY

Examiner

Myron G. Hill

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6- 18 is/are pending in the application.
- 4a) Of the above claim(s) 7- 11, 17, and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, and 12- 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 7- 11, 17, and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. This action is in response to amendment filed 12/23/2003.

This action is on claims 6 and 12- 16.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The rejection of claims 12- 16 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention because the term "increasing the efficiency" has been removed from the claims.

Claim Rejections - 35 USC § 102

The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Ramalingam is withdrawn because that claims have been amended and are no longer anticipated by the reference.

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The rejection of claims 6 and 12- 16 under 35 U.S.C. 102(b) as being anticipated by Vollmer is withdrawn because that claims have been amended and are no longer anticipated by the reference.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

Claims 6 and 12- 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the claims have been amended to indicate that DNA is introduced into the cell, that the method has been clarified by now specifying “double-stranded breaks in DNA”, and that the term “increasing efficiency” has been removed from the claim.

Applicant's arguments have been fully considered and not found persuasive.

Applicant has not addressed the rejection that the method results in the outcome stated in the preamble.

It is now clear what is introduced into the cell and “increasing efficiency” has been removed from the claims.

New Rejections Necessitated By Amendment

Claim Rejections - 35 USC § 112

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Claims 6, and 12- 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been amended to recite the word "containing" certain elements. This term does not appear to be specifically defined in the specification. The term is considered to indicate "open" language and thus the claims are not limited to the recited elements. The terms "comprising" and "consisting" are preferred terms that are well understood and it is suggested that one of those terms be used. For the purpose of this Office Action, the term "containing" is taken to mean the same as comprising.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 12- 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vollmer *et al.* (cited as Vollmer in the previous action).

The claims are drawn to a method of introducing into a cell DNA comprising E4 orf6 and E1B.

Vollmer *et al.* discloses a method of improving the efficiency of chemotherapeutic agents with adenovirus E4 orf6 in mice (page 4369, column 2, lower half, page 4371, column 2, lower half, and Figure 6).

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Vollmer *et al.* teach that E1B is capable of binding to and inactivating the p53 gene product and this is useful to overcome the ability of cells to restrict viral replication (page 4369, sentence spanning column 1 and 2).

Vollmer *et al.* is silent on E4 orf 6. The virus was grown on 293 cells which only complement E1 mutant adenoviruses; therefor, the virus must have E4 orf 6.

One of ordinary skill in the art would have been motivated to add the E1B gene to the E4 orf-6 expressing DNA because 50- 80% of hepatocellular carcinomas have normal p53 (page 4369, paragraph 1). Also, it is known in the art that E1B and E4-orf6 are known to physically and functionally interact.

Thus it would have been *prima facie* obvious to modify the E4 orf-6 expressing DNA of Vollmer *et al.* with the E1B as taught by Vollmer *et al.* with the expectation of success in making an E4 orf-6 expressing DNA that has ability to overcome the cell block of viral replication.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramalingam *et al.* (cited in the last Office Action as Ramalingam) and Vollmer *et al.*

Ramalingam *et al.* discloses an adenovirus that expresses E4 orf 6 (construct 5, page 2936, column 2, second full paragraph).

While Ramalingam *et al.* is silent on the exact effect of E4 orf 6, the method comprises the same step of introducing into the cell the gene product of E4 orf6 by way of adenovirus infection.

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Ramalingam *et al.* does not disclose specifically adding back the E1B coding gene.

Vollmer *et al.* teach that E1B is capable of binding to and inactivating the p53 gene product and this is useful to overcome the ability of cells to restrict viral replication (page 4369, sentence spanning column 1 and 2).

One of ordinary skill in the art would have been motivated to add the E1B gene to the E4 orf-6 expressing DNA of Ramalingam *et al.* because 50- 80% of hepatocellular carcinomas have normal p53 (page 4369, paragraph 1). Also, it is known in the art that E1B and E4-orf6 are known to physically and functionally interact.

Thus it would have been *prima facie* obvious to modify the E4 orf-6 expressing DNA of Ramalingam *et al.* with the E1B as taught by Vollmer *et al.* with the expectation of success in making an E4 orf-6 expressing DNA that less susceptible to inhibition of viral DNA replication caused by p53.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MA

Myron G. Hill
Patent Examiner
May 2, 2004

James C. House
JAMES HOUSEL 5/3/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600